AstraZeneca

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SENT VIA UNITED PARCEL SERVICE

Ms. Frances Turner
Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Dear Ms. Turner:

Re: Docket Number 96D-0009
Response to FDA Call for Comments

Reference is made to the International Conference on Harmonization (ICH) Draft Revised Guidance entitled, "Q3B(R) Impurities in New Drug Products."

AstraZeneca Pharmaceuticals LP reviewed this guidance and sent comments to the docket referenced above on September 15, 2000. It has come to our attention that our submission, containing comments on Q3B(R), inadvertently contained a confidentiality statement that would not allow the FDA to disclose our comments to the public docket without written authorization.

The purpose of this letter is to state that AstraZeneca authorizes the FDA to disclose information in the original submission. A copy of our comments, without the confidentiality statement, is attached for re-submission to the docket. We understand that our comments will still be accepted for use in the docket.

AstraZeneca thanks you for notifying us that our original submission could not be legally used in the public docket with the confidentiality statement enclosed therein, and for the opportunity to re-submit comments on this important guidance.

Please direct any questions or requests for additional information to me, or in my absence, to Louis Kovach at (302) 886-5625.

Sincerely,

Carol Stinson-Fisher

Carol Stinson-Fisher
Technical Regulatory Manager
Technical Regulatory Affairs
Telephone: (302) 886-8074
Fax: (302) 886-2822

CSF/mrsc
Attachment

US Regulatory Affairs
AstraZeneca Pharmaceuticals LP
1800 Concord Pike PO Box 8355 Wilmington DE 19850-8355

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AstraZeneca

SENT VIA UNITED PARCEL SERVICE SEP 15 2000

Dockets Management Branch
Food and Drug Administration
HFA No. 305, Room No. 1061
5630 Fishers Lane
Rockville, MD 20852

Dear Sir or Madam:

Re: Docket No. 96D-0009
Response to FDA Call for Comments

Reference is made to the International Conference on Harmonisation (ICH) Draft Revised Guidance entitled "Q3B(R) Impurities in New Drug Products."

AstraZeneca Pharmaceuticals LP has reviewed this guidance and has the following comment:

- Section 2.2, paragraph 3. The first sentence could be clarified, e.g. 'Degradation products present at a level less than or equal to (≤) the threshold generally would not need to be identified.'

Please direct any questions or requests for additional information to me, or in my absence, to Louis Kovach at (302) 886-5625.

Sincerely,

Carol Stinson-Fisher

Carol Stinson-Fisher
Technical Regulatory Manager
Regulatory Affairs
(302) 886-8074
(302) 886-2822 (fax)

CSF/PC/mac

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